Attachment 1

CONSULTATION REPORT

U.S. DEPARTMENT OF JUSTICE FEDERAL BUREAU OF PRISONS

Name: KREMBEL, MICHAEL Reg. #: 016452-055 DOB: 02/28/1944	Referred By: BUTNER FCI Attending: KATZ, STANLEY

CHIEF COMPLAINT: History of squamous cell carcinoma.

Date of Visit:	Dictation Received:	Dictation Transcribed:
07/08/2013	07/08/2013	07/08/2013

Sensitive but Unclassified

CONSULTATION REPORT

The patient presents with a history of a squamous cell carcinoma on the central scalp which was treated with a surgical procedure and a flap repair. Over the last few months, the patient has had an apparent recurrence in the same area in the region of the flap, which represents an ulcerative large nodule lesion that is somewhat tender and firm to the touch.
IMPRESSION: Recurrent squamous cell carcinoma in the area of previously treated squamous cell carcinoma with flap repair.

PLAN: It is my strong opinion that the patient is a candidate for Mohs micrographic surgery, not only for the obvious reasons as stated above but also because of the location and the increasing size over the last few months in an area of a flap repair. This would be the true standard of care, and frankly due to the patient's good health and ability to tolerate such a procedure, I know nothing else that would be adequate other than this treatment. The patient will return for follow up in approximately one month for evaluation, assuming the Mohs surgery is done as soon as possible, which I again strongly recommend. This was discussed with the patient's family physician, Dr. Amy Rosenthal, and we both seem to concur with this suggestion.

Signature:
Stanley Katz, MD

SK
Electronically Signed 07/09/2013 09:00

Job No: 514394

4C

63

Attachment 2.

U.S. Department of Justice

Federal Bureau of Prisons

Federal Correctional Complex

Federal Medical Center
P. O. Box 1600
Butner, NC 27509

FROM: FCC Butner Utilization Review Committee

SUBJECT: Medical Consult Review

TO: Inmate Krembel Michael
Reg. No.: 16458-055
Unit: FMC 4C

Your medical consult for MOHS procedure has been

- [x] Approved
- [ ] Deferred
- [ ] Denied

at this time. The Utilization Review Committee concluded that the present consult is

- [x] Acceptable
- [ ] Necessary
- [ ] Mandatory
- [ ] Convenience of Inmate
- [ ] Not Medically Necessary
- [ ] Alternative Treatment Plan

consisting of _____

_____

If the above medical consult is approved, the consult will then be scheduled based on prioritization at the next available appointment. In the meantime, you should continue to utilize sick call procedures an continue to work with you primary care clinician team regarding any medical concerns.

7/10/2013
Date

Acting Clinical Director
Utilization Review Chairman

cc: Medical Record

Revised (6/03)

10/15/2013 CONSULT W/ DR. COOK DUKE MED. CTR

Attachment 3
(2 pages)

DukeMedicine

KREMBEL,MICHAEL
MRN: D1316242
DOB: 2/28/1944, Sex: M
Enc. Date:10/15/13

Notes (continued)

Providers Only (continued)

I saw Mr. Michael Krembel, an incarcerated inmate from the Federal Prison System today for the evaluation of a presumed recurrent squamous cell carcinoma of the scalp. Additional information regarding Mr. Krembel's initial evaluation can be found in his database consultative note.

To summarize, Mr. Krembel is an 69 year old Caucasian male who underwent the surgical excision of a histologically-confirmed squamous cell carcinoma of the scalp earlier this year. He has had at least two surgical excisions of this tumor, and his wound was reconstructed with a rotation flap. He had postoperative wound infectious complications that resolved with intravenous antibiotics. Previous CT and MRI staging examinations failed to show any lytic bone involvement. Mr. Krembel's tumor was excised in April, 2013. The excision revealed a moderately to well-differentiated keratinizing squamous cell carcinoma with involvement of a deep inked margin. Mr. Krembel's tumor was re-excised in early May, 2013, and by his consultative notes, the operative surgeon evidently excised the prior margin where deep tumor involvement had been appreciated. Histologic examination of that excision specimen failed to reveal any evidence of persistent squamous cell carcinoma, and the wound was reconstructed with a rotation flap. Mr. Krembel developed clinical evidence of a recurrent squamous cell carcinoma at this site shortly after his rotation flap repair. He was seen by a prison bureau physician on July 8, 2013, and that physician recommended a referral for consideration of the Mohs surgical excision of this presumedly recurrent squamous cell carcinoma, and I saw Mr. Krembel today for this evaluation.

On examination, Mr. Krembel had a well-healed rotation flap in the right crown and vertex area. There were obvious areas of cicatricial alopecia. Additionally, there was a dog-ear protuberance at the pivot point of the flap on the right posterior scalp. At the leading edge of the flap near the central portion of the scalp, Mr. Krembel had an approximately 2-3 cm keratotic nodule with central necrosis. This appeared to represent a clinically recurrent squamous cell carcinoma. On examination, which was limited by the patient's tenderness, the tumor appeared to extend at least to the depth of the underlying periosteum. There were no palpable suggestions of regional lymphadenopathy.

Mr. Krembel was referred to me for a discussion of therapeutic alternatives. He did have a radiation oncology consult in June, 2013. At that time, he had healing wounds on his scalp, but the radiation oncologist noted no obvious suggestions of clinically persistent neoplasia.

I discussed the presumed diagnosis of recurrent squamous cell carcinoma with Mr. Krembel at length. I informed him that no medical or surgical therapy could "guarantee" a permanent escape from eventual regional or distant metastatic disease. I agreed with the prison staff physician that the Mohs surgical excision of this neoplasm would likely have the highest possibility of local tumor control. The Mohs technique was described to Mr. Krembel at length. I have prepared him for the fact that the Mohs surgical excision of this squamous cell carcinoma, which will be confirmed with a biopsy procedure immediately prior to surgical excision, would likely involve an excision of the full-thickness of the scalp down to and including the periosteum. By palpation examination today, Mr. Krembel's squamous cell carcinoma appeared to be rather deep; and I have also mentioned to him that there were certainly possibilities that the underlying calvarium could be involved. Mr. Krembel has had prior radiographic examinations, as noted above, that have failed to reveal any evidence of calvarial involvement. I informed Mr. Krembel that I generally would not favor a repeated imaging study given the possibility of false negative results in this clinical setting and given his extensive scarring in this area. Rather, I would favor a Mohs surgical excision of this neoplasm with detailed analysis of the peripheral and deep surgical margins. Because there would be a rather large area of exposed bone following the surgical excision of this tumor, I informed Mr. Krembel that I would generally favor coordination of the Mohs surgical

DukeMedicine

KREMBEL,MICHAEL
MRN: D1316242
DOB: 2/28/1944, Sex: M
Enc. Date: 10/15/13

Notes (continued)

Providers Only (continued)

The importance of routine follow-up care with a general dermatologist was stressed to the patient.

I have prospectively discussed with the patient all commonly used treatment techniques for this neoplasm. The relative risks of, benefits of, and alternatives to each treatment technique were thoroughly discussed prior to the initiation of any surgical care.

- Informational literature handed out on skin cancer, skin cancer treatment, Mohs surgery, and preoperative instructions.
- The warning signs for skin cancer were reviewed.
- Preoperative skin cancer surgery counseling given.
- Nature of patient's diagnosis, prognosis, and treatment options were discussed in detail which include nature of non-melanoma skin cancer, and its potential to metastasize.
- Risks, benefits, and possible complications of each discussed in detail.
- Nature of Mohs surgery completely outlined and brochure provided. Patient acknowledges receiving and reviewing pamphlet.
- Complications and side effects of surgery discussed which include: pain, infection, bleeding/ hematoma, 100% scar formation, wound dehiscence, failure of flap or skin graft, distortion/alteration of surrounding anatomic features, temporary or permanent nerve damage, tumor recurrence.
- Repair options of CLO, flaps, grafts, second intention healing, and option of referral for repair discussed.
- Inability to predict postoperative size or method of repair in advance discussed.
- Patient was warned to stop smoking one week before and one week after surgery, since failure to do so can result in decreased flap and graft survival.
- All of the patient's questions and concerns were addressed.

Plan:
- Mohs' surgery will be scheduled.
- Photographs of concerning lesions obtained.

Comments: The potential for introducing an area of scarring alopecia was carefully explained to the patient.
I have explained to the patient that this tumor does possess some metastatic potential, and that this surgery cannot entirely eliminate the potential for distant disease.
I have prospectively informed the patient that the surgical defect created to remove this tumor may be quite large, and that such a large wound might require significant efforts to reconstruct.
The biopsy site was prospectively identified by the patient and confirmed by the physician using a mirror.
I have offered to arrange to have a plastic surgeon repair this wound.
I have prospectively discussed with the patient all commonly used treatment techniques for this neoplasm. The relative risks of, benefits of, and alternatives to each treatment technique were thoroughly discussed prior to the initiation of any surgical care.

Electronically signed by Jonathan Lambert Cook, MD at 10/16/2013 5:27 PM

Progress Notes signed by Jonathan Lambert Cook, MD at 10/16/2013 1:16 PM

Author:	Jonathan Lambert Cook, MD	Service:	(none)	Author Type:	Physician
Filed:	10/16/2013 1:16 PM	Note Time:	10/16/2013 12:46 PM		

MOHS ADDENDUM TO CHART

6

U.S. Department of Justice

Federal Bureau of Prisons

Federal Correctional Complex

Attachment 4

Federal Medical Center
P. O. Box 1600
Butner, NC 27509

FROM: FCC Butner Utilization Review Committee

SUBJECT: Medical Consult Review

TO: Inmate Krenbel Michael
Reg. No.: 16452-055
Unit: FMC ACU

Your medical consult for Plastic Surgery has been

- [x] Approved
- [ ] Deferred
- [ ] Denied

at this time. The Utilization Review Committee concluded that the present consult is

- [x] Acceptable
- [ ] Necessary
- [ ] Mandatory
- [ ] Convenience of Inmate
- [ ] Not Medically Necessary
- [ ] Alternative Treatment Plan

consisting of: _____

If the above medical consult is approved, the consult will then be scheduled based on prioritization at the next available appointment. In the meantime, you should continue to utilize sick call procedures an continue to work with you primary care clinician team regarding any medical concerns.

10/8/14
Date

Acting Clinical Director

Revised (5/03)

cc: Medical Record

Attachment 5
(2 pages)

CONSULTATION REPORT

U.S. DEPARTMENT OF JUSTICE FEDERAL BUREAU OF PRISONS

Name: Krembel, Michael **Reg. #:** 16452-055 **DOB:**	**Referred By:** BUTNER FCI **Attending:** CUSCELA, DANIEL
Followup History and Physical.	

Date of Visit:	Dictation Received:	Dictation Transcribed:
12/03/2013	12/03/2013	12/04/2013

Sensitive but Unclassified

RADIATION THERAPY REPORT

The patient was seen in consultation yesterday, 12/02/2013. He was seen prior back in June and has a diagnosis of a squamous cell carcinoma of the scalp. He underwent a surgical resection with complications in early May of that year, followed by a rotational flap with all margins apparently being negative. Due to the fact that he had the complications from the initial surgical procedure and he had no signs of recurrence and negative pathology on reexcision and reviewing the pathology with the patient, he felt that he wished to be followed. On my second evaluation he is noted to have a small nodule at the end of the skin of the flap, and it was unsure whether this was recurrent or an underlying suture. He was referred to Dermatology and felt that he needed a Mohs surgery and biopsy of this area. However the mass has grown quite rapidly, exophytically and ulceratively with a crater and signs of an infectious process and drainage as well as necrosis. He has a plastic surgery appointment but after examining the patient, clinically he appears to be a T4 with invasion into the skull, and is not a surgical candidate at this point. In light of the above findings, the patient agrees and wishes to proceed with diagnostic CT of the head with noncontrast to determine depth of invasion and/or invasion of the skull if present, to be followed by radiation therapy as the primary treatment. Since this mass is on the vertex of the skull, it should be easily approachable with tangential fields limiting the underlying brain and probably mixed with electrons as well for local control. We referred to NCCN guideline 2.2013 for squamous cell carcinoma of the skin, both recurrent and persistent, and are following guidelines with recommendations. The patient agrees to proceed. Does not wish any further surgery and wishes to proceed with radiation alone. I have arranged a cancellation of the plastic surgery consultation and will proceed with the above plan. His past medical and surgical history are unchanged.
REVIEW OF SYSTEMS: The patient states that he has no unusual feelings on the scalp, no crawling or creeping or sensations along the scalp. He does notice an odor and drainage on the pillow when he wakes up in the morning. It goes from a crusty type of exophytic growth to a weepy type of scab that bleeds. At this point, it is dry on evaluation. He is seen with physics and dosimetry on my consultation.

I discussed the case with Dr. Carden in medical oncology as well.

PLAN: The above consultation has been reviewed as well as my prior notes and pathology. Since the patient is now a T4 persistent disease, since he has not had time for recurrence and most likely had persistent disease at that site, he will be treated with primary radiation since he is not a surgical candidate for cure. At this point, we will proceed as planned with diagnostic CT as well as the planning CT and positioning for primary radiation treatment. Dr. Carden is

aware and will follow the patient along. He does not have a risk for multiple squamous cell carcinomas, and will not be offered any adjuvant or neoadjuvant chemotherapy.

Signature: Daniel Cuscela, MD

DC
Electronically Signed 12/05/2013 14:19

Job No: 755857

Attachment 6
(2 pages)

Medical Summary for Michael Krembel, 16452-055

Date: October,21st 2014; 03:45pm

Michael Krembel is a 70 year-old white male, whose most significant medical problem is very aggressive, recurrent metastatic squamous cell carcinoma of the scalp. It was initially diagnosed and treated in Trenton, NJ. Resection of the scalp tumor was done with 2 skin grafts taken from right thigh in April of 2013. Re-excision was performed in May of 2013. Since he has had two failed attempts of flap grafts to cover his scalp wounds, he was sent to FMC, Butner, NC for further management on 06/06/2013.

He was evaluated by a Dermatologist on 07/08/2013 who recommended for him to have MOHS surgery. This surgery was approved by the URC on 07/10/2013. Unfortunately this surgical procedure was not scheduled at all, reason is not clear to me. This however resulted in the delay in care of his cancer treatment. His cancer progressed during this time. He was then evaluated by the Oncology services of this facility in December of 2013. At that point it was decided by radiation Oncologist that he could be best treated by radiation therapy rather than MOHS surgery and his plan of care was changed. Patient completed his radiation treatment on June 23rd, 2014. After his radiation treatment he developed a large exophytic, ulcerative and bleeding mass covering the entire vertex of his scalp with nodularity adjacent to that area. Daily dressings were done but despite his aggressive wound management by P.T. services it continued to become worse.

On July 22, 2014 he underwent wide radical excision of the scalp SCC (20x20 cm in size) with partial craniectomy. After the resection bolster dressing of Xeroform and gauze were placed over the denuded and partially resected cranium. Histo Pathology report of the resected calvarium showed bone infiltrated by moderately differentiated Squamous Cell Carcinoma.

Patient was readmitted at DUMC on 08/18/14. During this admission he underwent a prolonged extensive neurosurgical and Plastic surgery procedures on 08/19/2014 which involved free muscle flap of the scalp, split thickness skin grafting of the scalp, partial craniectomy for osteomyelitis and involvement of the skull bone with infiltrating SCC and cranioplasty for skull defect of more than 5cm with a Titanium mesh plate. He was discharged back to the Oncology Outpatient floor on 08/25/2014. During this surgery he also developed acute weakness of his right upper and both lower extremities most likely due to CVA. Post-operatively he developed MRSA infection of the wound which required I.V. antibiotic treatment with Vancomycin. He was then sent to ACU for his care on 09/08/2014. His muscle flap got necrotic on the right one third of his scalp where he has an open wound with visible Titanium plate. His wound is clean and edges are healthy. His weakness of right upper and both lower extremities is improving and he is now able to stand up and walk up to the toilet in his own room. He can perform all activities of his daily living but he has difficulty walking even short distances without any support on the floor. He continues to get physical therapy.

He was seen by his plastic Surgeon for a follow up visit on 09/24/2014 who found a large mobile lymph node on the right side of his neck concerning for metastasis and recommended excision biopsy. Excision biopsy of this node was done by a General Surgeon on 09/26/2014 at FMC, Butner, NC. Biopsy report showed Invasive moderate to well differentiated Squamous Cell Carcinoma.

According to the Oncology services he does not need any radiation or Chemotherapy until he develops any more metastatic lesions or masses. He will need follow up PET scans every 3 to 4 months. According to his Plastic Surgeon he will need another extensive and prolonged plastic surgical procedure for the coverage of his scalp wound. Without this procedure he has very high risks of wound infection, Brain abscess, Meningitis, Septic shock and even death. Surgical procedure itself is not free from the risks of severe morbidity and mortality. Success of this surgical procedure is also unpredictable but benefits are more than the risks and patient is willing to go through this surgical procedure. This surgical procedure has been approved by the URC. Scheduling for this surgical procedure is awaited.

Mr. Krembel's other problems include: Hypertension, reflux esophagitis, hx of MRSA infection, and a right inguinal hernia which was repaired in 2009. He will continue to need skilled nursing care after discharge, as he still requires daily dressing changes of his scalp wounds. He is independent in his activities of daily living, but will need to continue physical therapy for muscle strengthening exercises and endurance. He will also need regular follow up visits with an oncologist for head and neck cancer treatment and general surgery follow up visits for wound care after discharge.

Patient's cancer is very aggressive and locally progressive. Probability of dying due to serious complications of his surgical procedures is more than the probability of dying from his cancer itself. However his life expectancy cannot be accurately predictable at this time.

From the Medical point of view he qualifies for the consideration of RIS due to his markedly debilitated general condition, advancing very aggressive metastatic Squamous Cell Carcinoma of the scalp and bed confinement at this point. Thank you.

Pushp K. Claudius, MD

Pushp K. Claudius, MD
Medical Officer, FCC Butner
BF6885163-087

ATTACHMENT 1

U.S. DEPARTMENT OF JUSTICE
Federal Bureau of Prisons
Mid - Atlantic Region

Butner Legal Center
P.O. Box 1600
Butner, North Carolina 27509

August 20, 2015

Bruce Berger
4800 Six Forks Road
Suite 100
Raleigh, NC 27609

Re: Administrative Tort Claim Number: TRT-MXR-2015-05022

Dear Mr. Berger:

Your administrative claim filed on behalf of Michael Krembel, 16452-055, has been considered for administrative settlement under the Federal Tort Claims Act, 28 U.S.C. § 2671, *et seq*. You state the Bureau of Prisons failed to timely act on the recommendations of Mr. Krembel's physicians and other health care providers which contributed to Mr. Krembel's deteriorating medical condition. You allege government liability in the amount of $750,000.00.

The claim was reviewed and Mr. Krembel received the standard of care for his medical condition. The Federal Tort Claims Act only provides compensation for loss of property or injuries resulting from the negligence, omission, or wrongful act of Bureau of Prisons employees acting within the scope of their employment. There is no evidence of staff negligence.

Therefore, your claim is denied. If you are dissatisfied with our determination, you may file suit in the appropriate United States District Court not later than six (6) months after the date of mailing of this notification.

Sincerely,

Matthew W. Mellady
Regional Counsel

cc: James B. Craven, III